

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS, INC. and
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. 22-513-RGA

MEMORANDUM ORDER

Before me is Plaintiff's Motion for Leave to File First Amended Complaint to Add Zhejiang Huahai Pharmaceutical Co., Ltd. ("Huahai") as Defendant. (D.I. 53). After that motion was briefed, Defendants filed a Motion for Leave to File Sur-Reply Brief in Opposition to Plaintiff's motion. (D.I. 64). I have considered the parties' briefing for both motions. (D.I. 54, 57, 59 (Plaintiff's motion); D.I. 64, 68 (Defendants' motion)).

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Third Circuit has construed Rule 15, instructing that "absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless 'denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.'" *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994)) (emphasis omitted). An amendment is futile if it "would fail to state a claim upon which

relief could be granted.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The futility analysis is the same as that which applies to a motion under Rule 12(b)(6). *Id.*

Defendants asserts that joinder of Huahai is “likely to delay the schedule by a year or more” based on the time needed for service of process on a foreign defendant, additional motions practice, and for Huahai to develop defenses through discovery. (D.I. 57 at 7–9). Plaintiff responds by arguing that it is possible that Huahai, based on its past practice in similar litigations, its contractual obligation to “fully cooperate with Teva and its counsels” in the present litigation, and other factors, will proceed in a manner that allows for its smooth integration into this case. (D.I. 59 at 5–6).

Plaintiff’s argument relies on several hypotheticals of how Huahai might litigate this case if added as a defendant. One such hypothetical is that “Huahai and Otsuka could reach an agreement . . . wherein Huahai is voluntarily dismissed after agreeing to provide discovery as if it were a party and to be bound by any judgment, order, or decision.” (D.I. 59 at 6).

I do not want to buy a pig in a poke. I cannot rest my adjudication of this motion on the chance that Huahai will adhere to Plaintiff’s proposed courses of action. Huahai would be entitled to conduct its own discovery, to develop its own defenses, and to file its own motions. Adding Huahai as a defendant presents the risk of months of delay, which may require postponing the October 15, 2024 trial and hinder my ability to issue a final judgment before the regulatory exclusivity date of April 23, 2025. (D.I. 57 at 8; D.I. 59 at 7). Should Defendants win this case, failure to timely adjudicate it could impact the launch of Defendants’ ANDA product, resulting in substantial prejudice to Defendants. (D.I. 57 at 8). Considering that it is pretty apparent that Otsuka’s primary purpose for joining Huahai is to obtain discovery from Huahai,

there is no justification for the increased risk of prejudice. (*See* D.I. 54 at 2, 12; D.I. 59 at 1–5; D.I. 53-3, Ex. B ¶¶ 55–63). Huahai is already contractually obligated to cooperate with Defendants in providing discovery. (*See* D.I. 54-2, Ex. D ¶ 2.1). I therefore find that granting Plaintiff leave to file an amended complaint will cause Defendants undue prejudice.

I also believe the proposed First Amended Complaint (D.I. 53-3, Ex. B) would be futile. Plaintiff has not raised a facially plausible claim that Defendants and Huahai are engaged in “an extensive collaboration . . . with respect to the preparation and filing of the ANDA and with respect to the manufacturing, marketing, distribution, and sale of Defendants’ ANDA Products upon FDA approval” and that therefore Huahai infringes its patents. (D.I. 59 at 8–9). The First Amended Complaint largely relies on “information and belief” pleading. (D.I. 53-3, Ex. B, ¶ 29–34, 65–67, 69–73, 80–83). As fact discovery has been ongoing and many documents have already been exchanged, Plaintiff fails to plead with the requisite specificity. *Cf. Belcher Pharms., LLC v. Int’l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331–32 (D. Del. 2019) (recognizing that Hatch-Waxman plaintiffs may plead with a lower level of specificity based in part on the difficulty patent owners face in obtaining information about accused products prior to discovery).

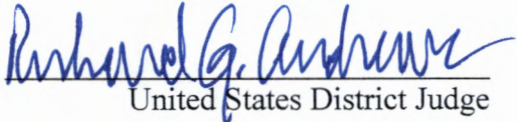
The remaining allegations that are not plead “upon information and belief” appear to be either conclusory or reliant on the Master Supply Agreement. (*See* D.I. 53-3, Ex. B ¶ 16–28). The factual allegations Plaintiff makes based on the Master Supply Agreement only present enough for me to draw the reasonable inference that Huahai acts as Defendants’ supplier, rather than as their joint partner. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility of entitlement to relief.” (internal quotation marks omitted)).

For the reasons set forth above, Plaintiff's Motion for Leave to File First Amended Complaint (D.I.53) is **DENIED**.

As I find it unnecessary to consider further briefing on Plaintiff's motion, Defendants' Motion for Leave to File Sur-Reply Brief (D.I. 64) is **DISMISSED** as moot.

IT IS SO ORDERED.

Entered this 20th day of October, 2023


United States District Judge